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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,635	03/24/2004	Jun Feng	DPP-IV-5004-U	8938

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TAKEDA SAN DIEGO, INC.  
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EXAMINER
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HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/809,635

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-17, 19, 20, 22-25, 27, 38, 52-54, 56 and 111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-17, 19, 20, 22-25, 27, 38, 52-54, 56 and 111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/19/07, 11/15/06, 9/25/06, 9/7/06 & 8/15/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 are pending in this application.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/2007 has been entered.

#### ***Response to Amendment***

3. Applicant's amendment filed 2/9/2007 in response to the previous Office Action (8/9/2006) is acknowledged. Rejections of claims 1-29, 37-39, 55 and 56 under 35 U.S.C. § 112, first and second paragraph (items 5 and 7a-7c) and the prior art rejection (item 6) have been obviated. Even though applicants overcome the rejections raised in previous Office Action, applicant's amendment raises new issue that needs further rejection.
4. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected

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invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Applicants have to delete the definition of Q = SO and SO<sub>2</sub> in response to this Office Action.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 8-9, 11-13, 16, 19, 23, 27 and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Kesarwani et al. *Tetrahedron Letters* 43 (2002) 5579-5581. Cited reference discloses two compounds of interest: 3-(phenylmethyl)-2-[4-(phenylmethyl)-1-piperidinyl]-4(3H)quinazolinone and 2-(4-methyl-1-piperazinyl)-3-(phenylmethyl)-4(3H)quinazolinone at page 5580 that are the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = benzyl (i.e. Z = CH<sub>2</sub> and R<sub>m</sub> = phenyl); and R<sub>2</sub> = piperidinyl substituted with benzyl or piperazinyl substituted with methyl.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9, 11-13, 16-17, 19, 23, 27 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Shimada et al. EP 1197799. Cited reference teaches 3-[5-[3,4-dihydro-4-oxo-3-(phenylmethyl)-2-quinazolinyl]-2,4-dioxo-3-oxazolidinyl]-4-methoxy-Benzoic acid, tetradecyl ester at page 19 (see compound 50) that is the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = benzyl (i.e. Z = CH<sub>2</sub> and R<sub>m</sub> = phenyl); and R<sub>2</sub> = substituted oxazolidinyl ring.

7. Claims 8, 15, 19, 23 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Abdel-Fattah et al. *Indian Journal of Heterocyclic Chemistry* (1999), 8(3), 177-182. Cited reference teaches a compound of interest 3-[(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)acetyl]-2-[4,5-dihydro-3-(2,4,6-trimethylphenyl)-1H-pyrazol-5-yl]-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = CO-CH<sub>2</sub>-1,3-dioxo-2H-isoindol; and R<sub>2</sub> = trimethylphenyl-substituted pyrazole ring.

The examiner has attached the abstract from STN chemical search printout that shows this compound.

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8. Claims 8, 11-14, 16, 22, 25 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Barnela et al. *Indian Journal of Chemistry Section B: Organic Chemistry Including Medicinal Chemistry* (1986), 25B(7), 709-11. Cited reference teaches a compound of interest: 3-(phenylmethoxy)-2-(1-phenyl-1H-pyrazol-4-yl)-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = O-CH<sub>2</sub>-phenyl; and R<sub>2</sub> = phenyl-substituted pyrazole ring.

The examiner has attached the abstract from STN chemical search printout that shows this compound.

9. Claims 8-9, 11-13, 16-17, 19, 27 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Soliman et al. *Journal of the Chemical Society of Pakistan* (1986), 8(2), 97-106. Cited reference teach two compounds of interest: 1-acetyl-3-(4-chloro-3-methylphenyl)-5-[3,4-dihydro-4-oxo-3(phenylmethyl)-2-quinazolinyl]-4,5-dihydro-1H-Pyrazole and 1-acetyl-3-(3-bromophenyl)-5-[3,4-dihydro-4-oxo-3(phenylmethyl)-2-quinazolinyl]-4,5-dihydro-1H-Pyrazole that are the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = CH<sub>2</sub>-phenyl; and R<sub>2</sub> = phenyl-substituted pyrazole ring.

The examiner has attached the abstract from STN chemical search printout that shows this compound.

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10. Claims 8-9, 11-13, 16-17, 25 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Rudolf et al. GB 2143542 A. Cited reference at page 10 (Example 10) teach a compound of interest: 2-(1-ethyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-6-quinolinyl)-3-(phenylmethyl)-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = CH<sub>2</sub>-phenyl; and R<sub>2</sub> = alkyl substituted quinoline ring.

11. Claims 8-9, 11-13, 19, 27 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Sammour et al. Egyptian Journal of Chemistry (1979), Volume Date 1976, 19(6), 1109-16. Cited reference teaches a compound of interest: 2-[4,5-dihydro-3-(4-methylphenyl)-1-phenyl-1H-pyrazol-5-yl]-3-(phenylamino)-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XI has the following substituents:

Q = CO; R<sub>1</sub> = NH-phenyl; and R<sub>2</sub> = phenyl-substituted pyrazole ring.

The examiner has attached the abstract from STN chemical search printout that shows this compound.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636. Although the conflicting claims are not identical, they are not



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patentably distinct from each other because there is significant overlap between the instant claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 and claims 1, 3-5, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 38 or elsewhere in the claims, the terms "aldehyde", "amide", "ester", and "ketone" are not clear. Said terms are molecules, but not moieties. One skilled in the art would consider these terms as molecules and not substituents or moieties.

b. In claim 38 (page 7) in the definition of  $R_{12}$ , the phrase "each  $R_{12}$  .....carbonyl group, ....oxo," is not clear. Oxo and carbonyl are recited as substituents for example on alkyl group. How is carbonyl substituent substituted on the alkyl group? Do applicants mean an oxo group substituted on alkyl? Note that carbonyl ( $C=O$ ) is

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different from an oxo group (=O). If a carbonyl is substituted on alkyl, the molecule becomes charged, because of the carbon atom that bears the oxo group.

### ***Information Disclosure Statement***

15. Applicant's Information Disclosure Statement, filed on 2/9/2007 (two IDS), 11/15/2006, 9/25/2006, 9/7/2006 and 8/15/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Note that one of the IDS submitted on 2/9/2006 contains (14 pages) list of references that are duplicates. The examiner has considered them on 8/9/2006.

### **Conclusion**

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned above the printed name.

Kahsay Habte  
Primary Examiner  
Art Unit 1624

March 12, 2007